CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65)

NOTICE TO INTERESTED PARTIES April 9, 2004

Request for Information on Progesterone (CAS# 57-83-0), A Chemical to be Considered by the OEHHA Science Advisory Board's Developmental and Reproductive Toxicant (DART) Identification Committee

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

The Developmental and Reproductive Toxicant (DART) Identification Committee of OEHHA's Science Advisory Board advises and assists OEHHA in compiling the list of chemicals known to the State to cause reproductive toxicity which is mandated by Health and Safety Code Section 25249.8. The Committee serves as the State's qualified experts for rendering an opinion as to whether a chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause reproductive toxicity.

In accordance with the OEHHA's process for preparing information on chemicals to be evaluated by the State's qualified experts, OEHHA will review the available reproductive toxicity literature and data on progesterone, and prepare a summary of the information. The DART Identification Committee will consider the OEHHA summary of reproductive toxicity information before making findings regarding whether progesterone should be added to the Proposition 65 list of chemicals known to the state to cause reproductive toxicity. Interested parties or members of the public wishing to provide information relevant to this assessment should forward such information to the address given below. The publication of this notice marks the start of a 60-day data call-in period. Interested parties or members of the public wishing to provide information relevant to the assessment of reproductive toxicity of progesterone should forward such information to the address given below. Relevant information includes but is not limited to: epidemiological and animal bioassay studies of male, female or developmental toxicity, in vitro test data, and other pertinent data on pharmacokinetics, biomarkers, and effects on biochemical and physiological processes in humans. A previous request for information relevant to the assessment of reproductive toxicity of progesterone was published in the California Regulatory Notice Register (Register 97, No. 52-Z) on December 26, 1997. Due to the delay in preparing the summary of information relevant to the assessment of reproductive toxicity of progesterone, OEHHA is opening this second 60-day data call-in period for the chemical.

This period ends on **Tuesday**, **June 8**, **2004**. The information received during this data call-in period will be reviewed and considered by OEHHA as it develops the draft reproductive and developmental toxicity hazard identification document on progesterone.

OEHHA welcomes public participation and public input as part of these scientific assessments. If there is sufficient public interest, a public workshop or other public forum will be held to encourage scientific dialogue prior to completion of the draft hazard identification documents.

Notification of the availability of the draft hazard identification document and of the time, date, location, and agenda of the DART Identification Committee meeting where progesterone will be discussed will be provided in future notices published in the *California Regulatory Notice Register* and posted on OEHHA's Home Page at http://www.oehha.ca.gov. It is anticipated that the draft hazard identification document will be made available for a 60-day public comment period prior to the committee meeting at which progesterone will be considered.

Relevant information on progesterone should be sent in **triplicate** by mail or fax to:

Cynthia Oshita
Office of Environmental Health Hazard Assessment
Proposition 65 Implementation
P.O. Box 4010
1001 I Street, 19th floor
Sacramento, California 95812-4010
FAX: (916) 323-8803

Telephone: (916) 445-6900

Relevant information may also be delivered in person or by courier to the above address. It is requested, but not required, that written comments and supporting documentation be transmitted via email addressed to: coshita@oehha.ca.gov. In order to be considered, the relevant information must be postmarked (if sent by mail) or received at OEHHA (if hand-delivered, sent by FAX, or transmitted electronically) by 5:00 p.m. on Tuesday, June 8, 2004.